

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug and Cosmetic Act]

2651-2670

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR,

Commissioner of Food and Drugs.

WASHINGTON, D. C., December 5, 1949.

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2651. Misbranding of gonorrhea treatments, sulfathiazole tablets, sleeping potion, and ephedrine and amytal capsules. U. S. v. Irvin A. Feld and Israel S. Feld (Super Cut Rate Drugs), and James W. Spriggs, Joseph D. Cabaniss, and Arlington D. Anderson. Pleas of nolo contendere. Fine of \$300 against Irvin A. Feld, \$300 against Israel S. Feld, and \$200 against each of the other defendants. Sentence of 60 days in jail also

*For presence of a habit-forming narcotic without warning statement, see Nos. 2651, 2652; omission of, or unsatisfactory, ingredients statements, Nos. 2651, 2657; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 2651, 2657, 2659; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 2651.

imposed against each defendant, to be served in event of nonpayment of fine. (F. D. C. No. 24247. Sample Nos. 42172-H to 42174-H, incl., 42176-H, 42177-H, 90312-H, 90314-H, 90316-H, 90343-H to 90345-H, incl.)

INFORMATION FILED: May 25, 1948, District of Columbia, against Irvin A. Feld and Israel S. Feld, partners, trading as Super Cut Rate Drugs, Washington, D. C., and against James W. Spriggs, manager of the drug department of the business, and Joseph D. Cabaniss and Arlington D. Anderson, pharmacists in the drug department.

ALLEGED VIOLATION: The defendants caused certain drugs to be misbranded in interstate commerce. Between the dates of November 13, 1946, and May 27, 1947, the defendants caused the sale in the District of Columbia of 3 *gonorrhea treatments* consisting of *sulfathiazole tablets*, accompanied by a bottle containing a copaiba emulsion; two *gonorrhea treatments* consisting of methylene blue compound tablets, accompanied by a bottle containing an aqueous solution of plant extractives and potassium acetate; and two *gonorrhea treatments* consisting of *oil of santal capsules*, one treatment accompanied by a copaiba emulsion and the other accompanied by an aqueous solution of plant extractives and potassium acetate.

The defendants caused also the sale in the District of Columbia of one lot of *oil of santal capsules*, one lot of *sulfathiazole tablets*, a "sleeping potion" consisting of a mixture of bromides and phenobarbital, and one lot of *ephedrine and amytal tablets*. Amytal contains a derivative of barbituric acid.

The drugs so caused to be sold by the defendants were misbranded because of failure to comply with the various labeling requirements of the law.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the products failed to bear adequate directions for use since they failed to reveal the conditions for which the drugs were intended; Section 502 (b) (1) and (2), certain of the products failed to bear a label containing a statement of the quantity of the contents and the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (d), the *sleeping potion* and the *ephedrine and amytal capsules* contained a chemical derivative of barbituric acid, which has been designated as habit forming, and their labels failed to bear the name and quantity or proportion of such derivative and the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1) and (2), with the exception of the *ephedrine and amytal tablets*, the labels failed to bear the common or usual names of the drug, in those instances involving a single drug, and failed to bear the common or usual names of the active ingredients in those drugs that were composed of two or more ingredients; also, in the case of three of the *gonorrhea treatments*, the labels failed to bear a statement of the quantity, kind, and proportion of alcohol present; and the label of the *sleeping potion* bore no statement containing the name and quantity or proportion of the bromides contained in the article.

Further misbranding, Section 502 (j), the *sulfathiazole tablets* in one of the *gonorrhea treatments* would be dangerous to health when used as directed in the labeling, "2 after meals," and the *sleeping potion* would be dangerous to health when used as directed since such use would result in the daily consumption of bromides in an amount which would be dangerous to health; and Section 502 (a), the directions "2 after meals" on the box of one of the lots

of *sulfathiazole tablets* were misleading since they implied that the product would be safe and appropriate for administration when used as so directed, whereas it was not safe and appropriate for use but was dangerous to health when so used.

DISPOSITION: October 28, 1948. Pleas of *nolo contendere* having been entered, the court fined both Irvin A. Feld and Israel S. Feld \$300 on each of counts 9 through 18, covering five of the *gonorrhea treatments* and the *ephedrine and amytal capsules*, and sentenced each individual to serve 60 days in jail in event of nonpayment. The fines were to run concurrently on each count. James W. Spriggs was sentenced to pay a fine of \$200 on each of counts 1 through 8, covering three of the *gonorrhea treatments*, the *sulfathiazole tablets*, and the *sleeping potion*, or to serve 60 days in jail in the event of nonpayment. These fines also were to run concurrently. Joseph D. Cabaniss and Arlington D. Anderson were given the same sentence as defendant Spriggs, covering charges in the case of defendant Cabaniss as set forth in counts 1, 2, 3, 4, 7, 9, 10, 15, and 16 relating to four of the *gonorrhea treatments* and the *sulfathiazole tablets*, and covering the charges in the case of defendant Anderson as set forth in counts 5, 6, 8, 11, 12, 13, 14, 17, and 18 relating to four of the *gonorrhea treatments*, the *sleeping potion*, and the *ephedrine and amytal capsules*.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2652. Misbranding of phenobarbital sodium capsules, phenobarbital tablets, and nembutal capsules. U. S. v. John Altergott (John Altergott Drug Co.). Plea of not guilty. Tried to the court. Verdict of guilty. Fine, \$175 and costs. (F. D. C. No. 25584. Sample Nos. 20517-K to 20520-K, incl., 20523-K, 20524-K, 20527-K.)

INFORMATION FILED: January 3, 1949, Western District of Missouri, against John Altergott, trading as the John Altergott Drug Co., Kansas City, Mo.

INTERSTATE SHIPMENT: Between the approximate dates of October 16, 1947, and June 4, 1948, from Bristol, Tenn., and North Chicago, Ill., to Kansas City, Mo., of quantities of *phenobarbital sodium capsules*, *phenobarbital tablets*, and *nembutal capsules*.

LABEL, WHEN SHIPPED: "Capsules Phenobarbital Sodium 1½ Grs. (0.1 Gm.)," "Tablets Phenobarbital 1½ GRS. (0.1 Gm.)," and "Capsules Nembutal (Pentobarbital Sodium * * *) 1½ grs."

ALLEGED VIOLATION: The products were made and labeled by the manufacturer to be dispensed only by or on the prescription of a physician. On or about June 25 and July 1, 2, 6, and 7, 1948, while the drugs were being held for sale after shipment in interstate commerce, the defendant removed portions of the drugs from the bottles in which they had been shipped, repacked them in cartons and envelopes, and sold them to various persons without a prescription, which acts of the defendant resulted in the drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (d), the articles were drugs for use by man and contained chemical derivatives of barbituric acid, which derivatives had been found by the Administrator of the Federal Security Agency after investigation to be, and by regulations designated as, habit forming;

*See also No. 2651.